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PRINCIPAL INVESTIGATOR: Jeffrey J. Shimon

CONTRACTING ORGANIZATION: SRI International

Menlo Park, California 94025-3493

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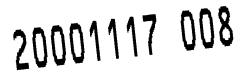
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Design of the existing RSMU prototype and production of the improved RSMU is complete. Qualitative evaluation of the upgraded RSMU at SRI shows it is possible to manipulate microsurgical sutures. However, improvements are indicated to alleviate deficiencies with the master console and video imaging system.

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TABLE OF CONTENTS

SF2	298	II
TAE	BLE OF CONTENTS	!!!
1.	INTRODUCTION	1
2.	BODY	1
3.	KEY RESEARCH ACCOMPLISHMENTS	6
4.	REPORTABLE OUTCOMES	6
5.	CONCLUSIONS	6
6.	REFERENCES	7
7.	PERSONNEL	7

1. INTRODUCTION

SRI International (SRI) is pleased to submit this final report, ITAD-10319-FR-00-113, to the U.S. Army Medical Research and Materiel Command (USAMRMC).

The research discussed herein is the development of a remote slave micromanipulator unit (RSMU) for the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, Maryland. The RSMU will extend the microsurgical capabilities of existing telepresence surgery systems (TeSSs) installed at both SRI and USUHS. The goal is to use SRI telepresence technology to enable surgeons to perform microsurgical procedures in shorter times, with better control of dexterous tissue manipulation and suture placement, and with less trauma to fine tissues than they could with conventional hand instruments. With the new micromanipulator, the TeSS will become a testbed where military surgeons can evaluate the potential benefits of remote telepresence microsurgery; this testbed will provide a changeable set of microsurgical instruments, zoomable micro-stereo-video images, and scalable hand motion reduction. This research includes the redesign of an existing RSMU prototype, the production of the improved RSMU for USUHS, the integration of the new RSMU with existing TeSS master consoles, and technical support for the testing and evaluation of the new system by USUHS surgeons and personnel.

It is noted that the material covered in this report overlaps significantly with the material covered in the Midterm Report: Telepresence Microsurgery for USUHS, ITAD-10319-TR-00-086. Much of the RSMU development effort was completed as of the Midterm Report, with few additions for the Final Report.

2. BODY

The research effort for the development of an RSMU for USUHS consists of four main tasks with associated subtasks. Progress and accomplishments with respect to each task are described below.

Task 1: Develop an Improved Design for the RSMU.

Prior to the current research, SRI had developed an early prototype RSMU with limited functionality. Under Task 1 we are designing, implementing, and evaluating specific hardware and software upgrades to the prototype RSMU that will make it an effective microsurgical testbed.

Subtask 1.1: Micromanipulators

The early prototype RSMU had only two general-purpose instrument end effectors, a needle holder and a pick-up. Changing these instruments required a mechanical disassembly process that took approximately 10 min, but microsurgical procedures require a variety of instruments and the ability to quickly change between instruments.

In cooperation with Dr. K. Scot Bower of Walter Reed Army Medical Center (Walter Reed), SRI has selected and purchased a set of ophthalmic surgery instruments for use with the

RSMU, including

- Curved and straight Barraquer needle holders
- Suturing and corneal forceps
- Tenotomy scissors
- Tying forceps, curved, angled, and straight.

Instrument holders and a threaded quick-disconnect exchange interface to the RSMU have been designed for the ophthalmic surgery set. The instrument holders, exchange interface, and RSMU gripping actuator enable the tools to operate smoothly and to be exchanged in 10 s or less. The sprung handles of the forceps instruments are delicately fabricated and calibrated by the manufacturers. Therefore, in designing the forceps instrument holders, we were careful to maintain the full length of the instrument handle so as to ensure smooth response. The needle holder and scissor handles were modified slightly to incorporate them into the RSMU. All of the instrument holders and exchange interfaces were designed to be roughly the same length, so that the workspaces they required would be similar. Figure 1, below, shows a selection of instruments from the ophthalmic instrument set.

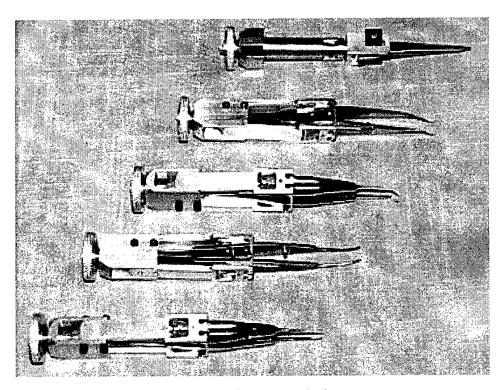


Figure 1. Selected Ophthalmic Instruments

SRI has also completed design modifications to improve reliability and diminish mechanical backlash in the original RSMU micromanipulators. The modifications include the preloading of bearings in all critical joints, the tightening of tolerances of precision parts, and the installation of cable-locking mechanisms to prevent cable actuator slippage. It is estimated that

backlash has been reduced 80% from that of the initial prototype: the positioning resolution at the tip of the tool is $7.5~\mu m$ and the backlash is less than 0.5~mm. Significant backlash still remains in the final roll axis of the tool; but the roll axis is not as critical as other factors in positioning the tool or handling sutures and tissue.

Subtask 1.2: Video Imaging

SRI has replaced the original dissecting RSMU microscope with a Zeiss OPMI-6-CFC* deployable surgical microscope on loan from the USUHS Department of Surgery. This microscope will be used in a time-sharing manner between the RSMU and its other obligations. Dr. Bower of Walter Reed has identified this microscope as adequate for our purposes. The microscope provides significantly more light than the dissecting microscope and has foot pedal controlled zoom and focus capabilities.

We designed and implemented a microscope mounting mechanism to position the microscope relative to the micromanipulator arms on a cart-top unit. The microscope and micromanipulators operate over an adjustable workspace table. This configuration should prove adequate for work on small test articles.

We originally proposed to provide aperture stops to the microscope to increase the depth of field. However, the optical technology used with the Zeiss OPMI microscope already maximizes the depth of field for the given light availability. Better depth of field can be obtained only from a more expensive microscope.

A set of high-resolution, triple-CCD color video cameras have been fitted to the Zeiss OPMI microscope via custom relay lenses. The CCD cameras have a horizontal resolution of 768 lines and a vertical resolution of 494 lines. The camera controllers provide automatic gain control and automatic black and white color balance. A locking adjustment mechanism has been implemented with the relay lenses to allow the fast and reliable setup of the horizontal convergence and vertical offset of the cameras' active visual fields within the microscope eyepieces.

Subtask 1.3: Control

The original RSMU had a very limited motion control capability. We therefore implemented electronic circuit modifications and software upgrades to enable the RSMU to be operated from a TeSS master console. The servo control allows a working volume from the master console of approximately $300\times300\times300$ mm. The circuit modifications are compatible with both the SRI and the USUHS systems and the software upgrades are fully transportable.

In order to enhance microsurgeons' fine hand motion dexterity, we implemented motion-scaling software to reduce hand motion in all axes except the final instrument roll. The software allows scale factors of 1:1, 2:1, and 4:1 to be set upon system initialization. Although originally proposed, motion scaling up to 20:1 is not feasible because of interference between the master manipulator arms.

In addition, scaling software has been implemented to augment instrument roll, providing

^{*} All product or company names mentioned in this document are the trademarks of their respective holders.

double pronation-supination. For example, a 45° roll of the master wrist provides a corresponding 90° roll in the slave instrument. The limited range of pronation-supination of the human wrist, coupled with the motion required by the hand master, necessitates this feature.

Deployable initialization fixtures and initialization software have been implemented to facilitate changes in scaling settings. The mechanical fixtures provide repeatable tool reference positions, while the initialization software automatically closes and registers both the slave and the master grippers. The mechanical fixtures can be swept out of the workspace area following initialization.

Subtask 1.4: Breadboard Testing and Evaluation

In order to test and evaluate the above design improvements to the RSMU, SRI, USUHS, and Walter Reed proposed to carry out mock surgical procedures. Performance measures such as suture placement accuracy, task completion times, and leakage rates were to be taken. A testing and evaluation session in which Dr. Bower of Walter Reed would perform various ophthalmic surgery tasks with the RSMU at SRI has been proposed. As of this final report, this session has not been executed due to lack of availability of Walter Reed staff.

In addition, SRI has received qualitative input regarding the performance of the upgraded microsurgery system from Dr. Rudy R. Buntic of the Bunke Microsurgery Clinic at the Davies Medical Center, San Francisco, California. Dr. Buntic attempted to manipulate 10-0 and 11-0 sutures and place the sutures in tissue paper, which is a standard test article for open microsurgical practice. The following observations were noted:

- System dexterity: The surgeon was able to manipulate an 11-0 needle and tie knots, although the time for the tasks was longer than with direct manipulation and vision.
- Imaging system: The surgeon had some difficulties visualizing the 11-0 sutures. Some of these difficulties were resolved by changes in lighting, but some were due to the resolution of the video system and ghosting of the stereo images.
- Master system: The surgeon experienced fatigue after a few minutes of work with the system. It was determined that the fatigue was mainly due to the forces needed to operate the tweezers and the inertia associated with movements of the master arm.
- Fine control of the tweezers grip: The time needed to pick up the needle was far greater with the system than with direct manipulation. It was determined that this discrepancy was due to the coarse control of the tweezers, which in turn is due partly to the friction in the master and partly to friction in the slave.

Some work was done to reduce friction in the RSMU instrument holders to address these issues. However, most of the problems experienced by the surgeon are caused by mechanical deficiencies of the TeSS master console and visualization system. Design modifications to those systems are outside the scope of this research.

Task 2: Build an Improved RSMU for USUHS

SRI has incorporated the design upgrades to the RSMU outlined in Task 1 and has completed the component purchase, fabrication, assembly, and debugging of an upgraded

RSMU. The RSMU is fully functional and ready for use by USUHS. We assume that quantitative testing and evaluation of the RSMU upgrades by USUHS and Walter Reed surgeons in Task 1.4 will require only minor modifications, if any, to the new RSMU hardware. The upgraded RSMU, including instrument holders, CCD cameras and relay lenses, and microscope mounting mechanism is shown below in Figure 2.

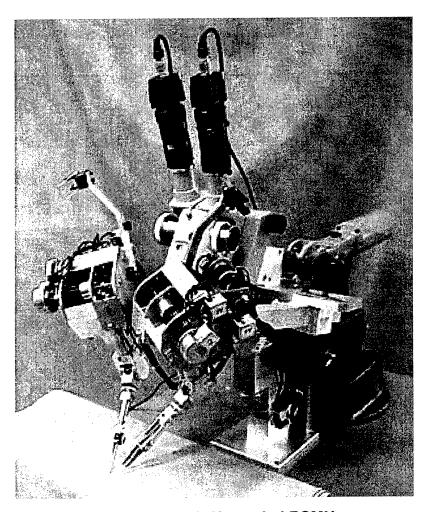


Figure 2. Upgraded RSMU

Task 3: Deliver the RSMU Prototype and Integrate with TeSS

We originally proposed to deliver the upgraded RSMU from Task 2 to USUHS and incorporate it with the TeSS master console already installed at USUHS. However, several issues suggest that it may be mutually beneficial for both SRI and USUHS to maintain the upgraded RSMU at SRI. As of this final report, the decision as to the disposition of the RSMU has yet to be made.

Task 4: Provide Technical Support

Technical support will be provided to USUHS staff and interested research surgeons at SRI or at USUHS, depending on the disposition of the RSMU delivered in Task 3.

3. KEY RESEARCH ACCOMPLISHMENTS

To date, the key research accomplishments of this project are as follows.

- The development of instrument holders and a quick-change interface for the ophthalmic surgery set
- Mechanical backlash reduction and robustness upgrade, which enable the RSMU to achieve a position resolution of 7.5 μm and a backlash of less than 0.5 mm
- The incorporation of a Zeiss deployable microscope with improved light and automatic focus and zoom
- The implementation of RSMU servo control with the TeSS master
- The implementation of 1:1 to 4:1 motion reduction and double pronation supination
- The development of initialization fixtures and software
- The qualitative evaluation of upgraded RSMU, which was found to allow the manipulation of 11-0 sutures
- The complete fabrication, assembly, and debugging of the upgraded RSMU.

4. REPORTABLE OUTCOMES

A grant proposal for \$400,000 [Ghastri and Garcia 2000], based on work with the eupgraded RSMU developed under this project, has been submitted to the National Medical Testbed (NMTB) in Loma Linda, California, for fiscal year 2000. Current grant work for NMTB in fiscal year 1999 has focused on the addition of two degrees of freedom to the RSMU design, master console improvements, and video imaging upgrades. Future work for NMTB would involve new developments for the video imaging system and master console.

5. CONCLUSIONS

The research development effort to improve the RSMU design and produce an upgraded prototype is complete (Tasks 1 and 2 above). The new RSMU should prove to be an adequate microsurgery demonstration and evaluation platform for USUHS surgeons and personnel. However, much development work is needed to make the RSMU a viable candidate for acceptance in the surgical field as a medical product. Qualitative evaluation of the new

microsurgery system indicates that further improvements to the master console and video imaging system would prove beneficial. In addition, performance of quantitative procedural tests of the system need to be performed.

6. REFERENCES

Ghastri, V., and P. Garcia. 2000. *Open Microsurgery System*, EMU 00-062, SRI International, Menlo Park, California (30 June).

Shimon, J. 2000. <u>Midterm Report: Telepresence Microsurgery for USUHS</u>, ITAD-10319-TR-00-086, SRI International, Menlo Park, California (14 July).

7. PERSONNEL

SRI personnel receiving pay from the research effort are listed below.

Raycroft, T.

Jacobson, L.

Crittenden, A.

Wilson, R.

Gorfu, Y.

Heim, J.

Garcia, P.

Shimon, J.

Shrader, E.

Jensen, J.

Low, T.

Stockett, J.

Mortensen, L.

Granados, M.